UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CÉSAR CASTILLO, INC., individually and on behalf of all those similarly situated,

Plaintiff,

v.

ACTAVIS HOLDCO U.S., INC., FOUGERA PHARMACEUTICALS, INC., PERRIGO COMPANY PLC, PERRIGO NEW YORK, INC., SANDOZ, INC., and TARO PHARMACEUTICALS USA, INC.,

Defendants.

Case No. 17-cv-250

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Plaintiff César Castillo, Inc. ("Plaintiff") files this civil action pursuant to Section 1 of the Sherman Act, Section 4 of the Clayton Act, and Rule 23 of the Federal Rules of Civil Procedure, for damages, costs of suit, and other relief as may be just and proper, on behalf of itself and a class of those similarly situated ("Class" as defined below) against Defendants Actavis Holdco U.S., Inc. ("Actavis"), Fougera Pharmaceuticals Inc. ("Fougera"), Perrigo Company plc ("Perrigo Ireland"), Perrigo New York, Inc. ("Perrigo NY")[1], Sandoz, Inc. ("Sandoz"), and Taro Pharmaceuticals USA, Inc. ("Taro USA"), (collectively "Defendants"), for Defendants' conspiracy to artificially fix, raise, maintain and/or stabilize the prices of generic desonide ("Desonide"). Based upon personal knowledge, information, belief, and investigation of counsel, Plaintiff specifically alleges as follows.

INTRODUCTION

1. This is a civil antitrust action seeking treble damages arising out of the Defendants' unlawful scheme to fix, maintain, and stabilize the prices of generic desonide ("Desonide").

2. Desonide is a widely prescribed topical corticosteroid that health care providers use to treat a variety of skin conditions, such as eczema and dermatitis. Because Desonide is a lower strength topical drug, physicians often prescribe it for pediatric patients or for adult patients to use in sensitive areas, like the eyelids.

3. Since at least 1994, manufacturers of generic drugs have had regulatory approval to market generic forms of Desonide. For much of that time, prices for generic forms of Desonide were low because generic manufacturers engaged in robust price

[1] Perrigo Ireland and Perrigo NY are together referred to as "Perrigo."

competition, as typically occurs among generic drug manufacturers in the absence of collusion.

4. Recently, however, Defendants have substantially increased the price of Desonide, in unison.

5. Beginning in July 2013, shortly after two meetings of generic pharmaceutical manufacturers attended by Defendants Fougera, Perrigo, Sandoz, and Taro, Defendants acted in concert to raise the price of Desonide in unison by a dramatic margin.[2] Although Actavis did not enter the Desonide market until November 2013, it too joined the conspiracy and implemented price increases. Those increases were the result of an agreement among Defendants to increase pricing and restrain competition for the sale of Desonide in the United States.

6. During a single week in July 2013, Defendants Fougera, Perrigo, Sandoz, and Taro collectively raised prices for Desonide more than six-fold, with certain product offerings increasing in price by more than 800%. Whereas, at the beginning of 2013, a 60-gram tube of Desonide cream cost $26.75, as of December 12, 2013, the cost was nearly $225.

7. Defendants' price increases were substantially in lockstep and Defendants' prices have stabilized at artificially high levels. As of December 2016, Desonide prices remain nearly more than 500% above their pre-July 2013 levels.

8. A report issued in August 2016 by the United States Government Accountability Office ("GAO") found that Desonide topical cream 0.05% and Desonide

[2] GAO, Report to Congressional Requesters, Generic Drugs Under Medicare: Part D Generic Drug Prices Declined Overall, but Some Had Extraordinary Price Increases (Aug. 2016), *available at* http://www.gao.gov/products/GAO-16-706.

topical ointment 0.05% both "experienced an extraordinary price increase" from 2013 to 2014.[3]

9. Defendants' price increases were contrary to their respective unilateral self-interests. Like any generic drug, Desonide is a commodity product. Therefore, absent a conspiracy or factors justifying a price increase, if any manufacturer substantially increased the price of Desonide, its competitors would not be expected to increase their prices by similar amounts, but would be expected seek to sell more Desonide to that manufacturer's customers. In other words, it would be contrary to any manufacturer's unilateral self-interest to substantially increase its price for Desonide unless it had agreed with the other manufacturers that they would do the same.

10. The only factors that would have justified such price increases would have been a significant increase in the costs of making Desonide, a significant decrease in the supply of Desonide, or a significant increase in demand for Desonide. None of those transpired in 2013. Absent these factors, substantial price increases would have been contrary to each Defendant's unilateral self-interest absent the existence of a cartel.

11. *Inter alia*, Defendants realized their conspiracy through private and public communications and meetings such as trade association meetings held by the GPhA. Given the small number of competitors and the high barriers to entry in the market for Desonide the market was ripe for collusion. Defendants recognized this and engaged in anticompetitive actions that allowed them to sustain their unlawful supracompetitive pricing.

12. Defendants' dramatic and unexplained price increases have resulted in extensive scrutiny by the United States Congress and federal and state regulators. In October

[3] *Id.*

2014, Congress sent letters to the heads of several drug manufacturers, including Defendants Actavis and Sun as part of an investigation "into the recent staggering price increases for generic drugs used to treat everything from common medical conditions to life threatening illnesses."[4]

13. No later than November 3, 2014, the Antitrust Division of the United States Department of Justice ("DOJ") commenced a wide-ranging investigation into generic drug manufacturers' marketing and pricing practices.

14. Defendants Taro, Fougera, Sandoz, Sun and Actavis have been subpoenaed by the DOJ's grand jury as part of its ongoing investigation of anticompetitive practices in the generic pharmaceutical industry.

15. These investigations have begun to reveal a reportedly broad, well-coordinated, and long-running series of schemes to fix prices, allocate markets, and rig bids for a number of generic drugs in the United States. These investigations have also revealed that Defendants' collusion on generic drug prices was centered around trade associations, such as the Generic Pharmaceutical Association ("GPhA"), customer conferences, and other industry gatherings. As part of these ongoing investigations, the DOJ convened a grand jury in the Eastern District of Pennslyvania. This grand jury has issued subpoenas and other requests for information to various generic drug manufacturers on a variety of generic drugs.

16. On December 14, 2016, the DOJ unsealed criminal informations against two former senior executives of generic drug manufacturer Heritage Pharmaceuticals Inc. for

[4] *See e.g.*, Letter from Sen. Bernard Sanders and Rep. Elijah E. Cummings to Brenton L. Saunders, Chief Executive Officer and President, Actavis plc (Oct. 2, 2014), *available at* http://www.sanders.senate.gov/download/letter-to-mr-saunders-ceo-and-president-actavis?inline=file.

violations of Section 1 of the Sherman Act for their roles in conspiracies to fix prices, rig bids, and allocate customers for generic drugs Glyburide and Doxycycline Hyclate DR. *See United States v. Glazer*, No. 16-cr-506 (E.D. Pa.) and *United States v. Malek*, No. 16-cr-508 (E.D. Pa.). The DOJ is reportedly preparing additional cases involving other generic drugs.

17. On December 15, 2016, twenty states attorneys general also filed their first action (relating to the generic drugs Glyburide and Doxycycline) based on their investigation into generic drug pricing. *See State of Connecticut v. Aurobindo Pharma USA, Inc.*, No. 16-cv-2056 (D. Conn.) (the "State AG Action").

18. According to the complaint in the State AG Action, the information developed through the AGs' investigation (which is ongoing) uncovered evidence of a broad, well-coordinated and long-running series of schemes to fix the prices and allocate markets for generic pharmaceuticals, beyond Glyburide and Doxycycline Hyclate DR. The complaint alleges that the conspiracies implicate numerous manufacturers.

19. As a result of Defendants' scheme to fix, raise, maintain, and stabilize the prices of Desonide, direct purchasers such as Plaintiff César Castillo, Inc., have paid and continue to pay supracompetitive prices.

20. Plaintiff RDC brings this civil antitrust action on behalf of a proposed class of direct purchasers of (1) Desonide topical cream 0.05% and (2) Desonide topical ointment 0.05% (collectively, "Desonide"). Plaintiff seeks overcharge damages arising out of Defendants' agreement not to compete in the market for Desonide.

JURISDICTION AND VENUE

21. This action arises under section 1 of the Sherman Act, 15 U.S.C. § 1 and section 4 of the Clayton Act, 15 U.S.C. § 15(a), and seeks to recover treble damages, costs of suit and reasonable attorneys' fees for the injuries sustained by Plaintiff and members of the Class resulting from Defendants' conspiracy to restrain trade in the United States. The Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1337(a), 1407, and 15 U.S.C. § 15.

22. Venue is proper in this District pursuant to 15 U.S.C. §§ 15(a), 22 and 28 U.S.C. §§ 1391(b), (c), and (d) because, during the Class Period, Defendants resided, transacted business, were found, or had agents in this District, and a substantial portion of their activity that affected the interstate trade and commerce discussed below has been carried out in this District.

23. During the Class Period, Defendants sold and shipped Desonide in a continuous and uninterrupted flow of interstate commerce, including in this District. Defendants' conduct had direct, substantial, and reasonably foreseeable effects on interstate commerce in the United States, including in this District.

24. This Court has *in personam* jurisdiction over Defendants because each, either directly or through the ownership and/or control of its subsidiaries, *inter alia*: (a) transacted business throughout the United States, including in this District; (b) participated in the sale and distribution of Desonide throughout the United States, including in this District; (c) had and maintained substantial aggregate contacts with the United States as a whole, including in this District; or (d) was engaged in an illegal price-fixing conspiracy that was directed at, and had a direct, substantial, reasonably foreseeable and intended effect of causing injury to,

the business or property of persons and entities residing in, located in, or doing business throughout the United States, including in this District. Defendants also conduct business throughout the United States, including in this District, and they have purposefully availed themselves of the laws of the United States.

25. By reason of the unlawful activities alleged herein, Defendants substantially affected commerce throughout the United States, causing injury to Plaintiff and members of the Class. Defendants, directly and through their agents, engaged in activities affecting all states, to restrict output and fix, raise, maintain and/or stabilize prices in the United States for Desonide, which unreasonably restrained trade and adversely affected the market for Desonide.

26. Defendants' conspiracy and unlawful conduct described herein adversely affected persons and entities in the United States who directly purchased Desonide manufactured by Defendants, including Plaintiff and the members of the Class.

PARTIES

A. Plaintiff

27. Plaintiff César Castillo, Inc. is a corporation organized under the laws of the Commonwealth of Puerto Rico, with its principal place of business and headquarters located at Bo. Quebradas Arena, Rd. #1 Km. 26.0, Rio Piedras, Puerto Rico, 00926. During the Class Period, Plaintiff purchased Desonide directly from one or more Defendants. As a direct and proximate result of Defendants' collusion, manipulative conduct, and unlawful acts, Plaintiff was injured in its business or property.

B. Defendants

28. Defendant Actavis Holdco U.S., Inc. ("Actavis") is a Delaware corporation with its principal place of business at Morris Corporate Center Ill, 400 Interpace Parkway,

Parsippany, New Jersey, 07054. During the Class Period, Actavis sold Desonide in this District and throughout the United States.

29. Defendant Fougera Pharmaceuticals Inc. ("Fougera Pharma") is a New York corporation with its principal place of business in Melville, New York. Fougera Pharma is a specialty dermatology generic pharmaceutical company that markets and sells generic Desonide throughout the United States. Fougera Pharma is now a wholly owned subsidiary of Defendant Sandoz, Inc. During the Class Period, Fougera Pharma sold Desonide products to customers in this District and other locations in the United States.

30. Defendant Sandoz, Inc. ("Sandoz"), is a Colorado corporation with its principal place of business in Princeton, New Jersey. Sandoz is a global leader in generic pharmaceuticals and biosimilars. In 2012, Sandoz acquired Fougera Pharma for $1.5 billion in cash, making Sandoz the top generic dermatology medicines company globally and in the United States. During the Class Period, Sandoz sold Desonide products to customers in this District and other locations in the United States.

31. Defendant Perrigo Company plc ("Perrigo plc") is incorporated under the laws of Ireland with its principal place of business in Dublin, Ireland. Perrigo plc's North American base of operations is located at 515 Eastern Avenue, Allegan, Michigan 49010, where Perrigo plc's domestic subsidiaries (Perrigo Company, a holding company; Perrigo Pharmaceuticals Co. and L. Perrigo Co., which are pharmaceuticals manufacturers; and Perrigo Sales Corp., a sales company), all Michigan corporations, are also located. Perrigo plc's prescription drug business focuses primarily on the manufacture and sale of extended topical prescription pharmaceuticals, such as Desonide.

32. Defendant Perrigo New York, Inc. ("Perrigo New York"), a Delaware corporation with offices at 1700 Bathgate Ave, Bronx, NY 10457, manufactures Perrigo's cream and ointment tubes, producing more than 50 million tubes annually. The officers and directors of Perrigo plc and these domestic Perrigo subsidiaries have been identical or substantially overlapping throughout the Class Period. During the Class Period, Perrigo plc, through its domestic subsidiaries, sold Desonide products to customers in this District and other locations in the United States.

33. Defendant Taro Pharmaceuticals USA, Inc. ("Taro") is a New York corporation with its principal place of business in Hawthorne, New York. During the Class Period, Taro sold Desonide products to customers in this District and other locations in the United States.

34. Various other entities and individuals currently unknown to Plaintiff may have also participated as co-conspirators in the acts complained of and/or performed acts that aided and abetted and/or otherwise furthered the conspiracy's objectives and unlawful conduct alleged herein.

35. The wrongful acts alleged to have been done by any one Defendant or co-conspirator were authorized, ordered, or done by its directors, officers, managers, agents, employees, or representatives while actively engaged in the management, direction, or control of such Defendant's or co-conspirator's affairs.

CLASS ALLEGATIONS

36. Plaintiff brings this action on behalf of itself and, pursuant to Federal Rules of Civil Procedure 23(a) and 23(b)(3), as representative of a class (the "Class") defined as follows:

> All persons who or entities which purchased Desonide directly from any of the Defendants, or any current or former subsidiary or affiliate thereof, or any co-conspirator, in the United States, during the period from and including August 1, 2013 through the present. Excluded from the Class are Defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all governmental entities.

37. The Class Members are so numerous and geographically dispersed that joinder of all members is impracticable.

38. Plaintiff's claims are typical of the claims of the other Class Members. Plaintiff and other Class members have all sustained damage in that, during the Class Period, they purchased Desonide at artificially maintained, non- competitive prices, established by the Defendants' actions in connection with the violations alleged herein.

39. Plaintiff will fairly and adequately protect the interests of all Class Members. Plaintiff has purchased Desonide directly from at least one of the Defendants. Plaintiff has retained counsel competent and experienced in class action and antitrust litigation. Plaintiff's interests are coincident with, and not antagonistic to, the interests of the other Class Members.

40. Common questions of law and fact exist with respect to all Class Members and predominate over any questions solely affecting individual members. The common legal and factual questions, which do not vary among Class Members include, but are not limited to, the following:

(a) Whether and to what extent Defendants and their co-conspirators engaged in a contract, combination, or conspiracy to fix, raise, maintain, or stabilize the prices of Desonide in the United States;

(b) The scope and duration of the contract, combination, or conspiracy, the identity of its participants, and the acts undertaken in its furtherance;

(c) The effect of the contract, combination, or conspiracy on the prices of Desonide in the United States during the Class Period;

(d) Whether and to what extent Defendants' conduct resulted in supracompetitive prices for Desonide;

(e) Whether and to what extent Defendants' conduct injured Plaintiff and other Class Members; and

(f) The appropriate measure of damages sustained by Plaintiff and other Class Members.

41. A class action is superior to any other method for the fair and efficient adjudication of these issues, as joinder of all members is impracticable. The damages suffered by many Class Members are small in relation to the expense and burden of individual litigation, and therefore, it is highly impractical for such Class Members to individually attempt to redress the wrongful anticompetitive conduct alleged herein.

INTERSTATE TRADE AND COMMERCE

42. Defendants are the leading manufacturers and suppliers of Desonide sold in the United States.

43. Desonide products are produced by or on behalf of Defendants or their affiliates in the United States and/or overseas.

44. During the Class Period, Defendants, directly or through one or more of their affiliates, sold Desonide throughout the United States in a continuous and uninterrupted flow of interstate commerce, including through and into this District.

45. The activities of Defendants and their co-conspirators were within the flow of, intended to, and had a substantial effect on interstate commerce in the United States.

46. Defendants and their co-conspirators' conduct, including the marketing and sale of Desonide, took place within, has had, and was intended to have, a direct, substantial, and reasonably foreseeable anticompetitive effect upon interstate commerce within the United States.

47. The conspiracy alleged in this Complaint has directly and substantially affected interstate commerce in that Defendants deprived Plaintiff of the benefits of free and open competition in the purchase of Desonide within the United States.

48. Defendants' agreement to inflate, fix, raise, maintain, or artificially stabilize prices of Desonide, and their actual inflating, fixing, raising, maintaining, or artificially stabilizing Desonide prices, were intended to have, and had, a direct, substantial, and reasonably foreseeable effect on interstate commerce within the United States and on import trade and commerce with foreign nations.

FACTUAL ALLEGATIONS

A. Overview of Generic Drug Market

1. Generic drugs lead to lower prices

49. Generic drugs typically provide consumers with a lower cost alternative to brand-name drugs while providing the same treatment. Specifically:

> A generic drug is the same as a brand name drug in dosage, safety, strength, how it is taken, quality, performance, and intended use. Before approving a generic drug product, FDA requires many rigorous tests and procedures to assure that the generic drug can be substituted for the brand name drug. The FDA bases evaluations of substitutability, or "therapeutic equivalence," of generic drugs on scientific evaluations. By law, a generic drug product must contain the identical amounts of the same active ingredient(s) as the brand name product. Drug products evaluated as "therapeutically equivalent" can be expected to have equal effect and no difference when substituted for the brand name product.[5]

[5] FDA, Generic Drugs: Questions and Answers, *available at* http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm.

50. Further, "[d]rug products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product."[6]

51. Generic versions of brand drugs are priced significantly below the brand versions. Because of the price differentials, and other institutional features of the pharmaceutical market, generic versions are liberally and substantially substituted for their brand counterparts. In every state, pharmacists are permitted (and, in some states, required) to substitute a generic product for a brand product unless the doctor has indicated that the prescription for the brand product must be dispensed as written. States adopted substitution laws following the federal government's 1984 enactment of the Hatch-Waxman Act (discussed in more detail below).

52. The FDA has recognized that "[g]eneric competition is associated with lower drug prices[.]"[7] A Federal Trade Commission study reached the same conclusion finding that in a "mature generic market, generic prices are, on average, 85% lower than the pre-entry branded drug prices."[8] Economic literature in the healthcare market further confirms that competition by generic products results in lower prices for consumers. In the period before generic entry, a brand drug commands 100% of the market share for that drug and the brand

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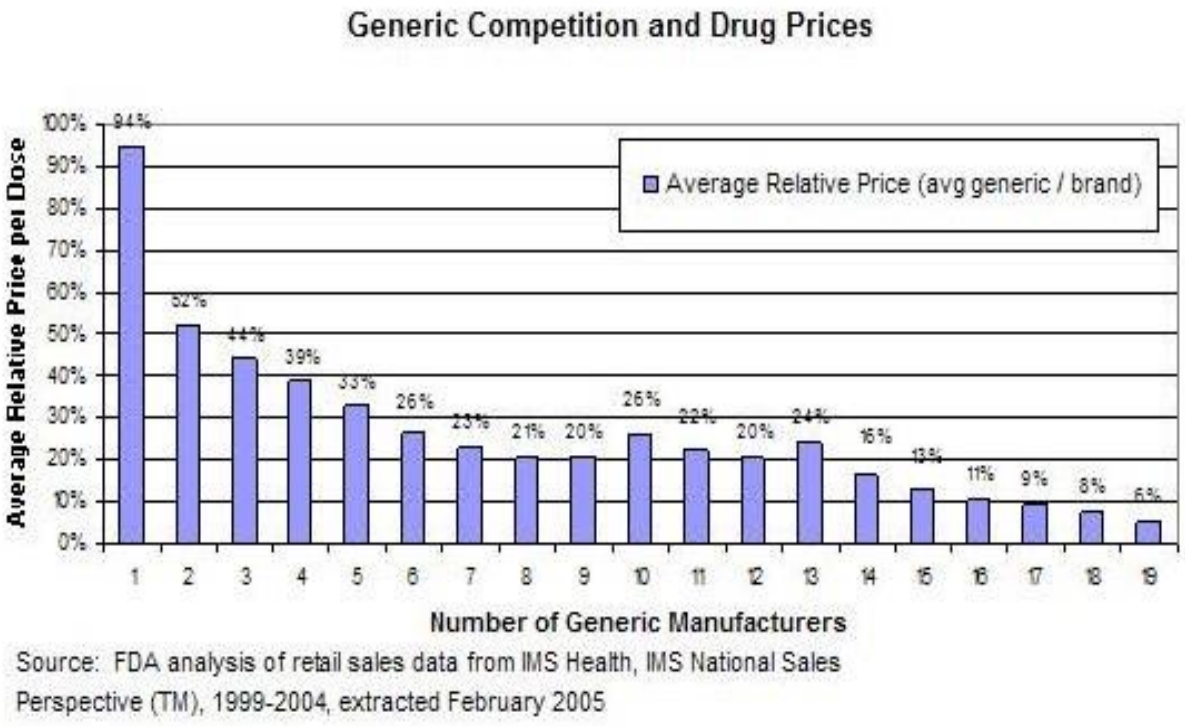
[6] *Id.*

[7] FDA, Generic Competition and Drug Prices, *available at* http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm.

[8] FTC, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS, at 8 (Jan. 2010), *available at* https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf.

manufacturer can set the price without the impact of competitive market forces. Once the first generic enters the market, however, a brand drug rapidly loses sales, on average 90% within a year. [9] As more generic manufacturers enter the market, prices for generic versions of a drug predictably will continue to decrease because of competition among the generic manufacturers, and the loss of sales volume by the brand drug to the corresponding generic accelerates as more generic options are available to purchasers:[10]



53. A mature generic market, such as the markets for Desonide, has several generic competitors. Due to the fact that each generic is readily substitutable for another generic of the same brand drug, the products behave like commodities, with pricing being the main

[9] *Id.*

[10] *See, e.g.*, Ernst R. Berndt et al., *Authorized Generic Drugs, Price Competition, and Consumers' Welfare*, HEALTH AFFAIRS, 26, no. 3 (2007):790-799.

differentiating feature and the basis for competition among manufacturers.[11] Over time, generics' pricing nears the generic manufacturers' marginal costs.

54. Generic competition usually enables purchasers to (a) purchase generic versions of the brand drug at a substantially lower price than the brand drug, and/or (b) purchase the brand drug at a reduced price. Generic competition to a single blockbuster brand drug product can result in billions of dollars in savings to direct purchasers, consumers, insurers, local, state, and federal governments, and others. Indeed, one study found that the use of generic medicines saved the United States healthcare system $254 billion in 2014 alone, and $1.68 trillion between 2005 and 2014.[12]

2. How generic drugs come to market

55. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers that create a new drug must obtain FDA approval to sell the product by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as information on applicable patents. 21 U.S.C. § 355(a), (b).

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[11] *See, e.g.*, FTC, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT, at 17 (Aug. 2011) ("[G]eneric drugs are commodity products marketed to wholesalers and drugstores primarily on the basis of price."), *available at* https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf; Congressional Budget Office, "How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry" (July 1998), *available at* https://www.cbo.gov/sites/default/files/105th-congress-1997-1998/reports/pharm.pdf.

[12] Generic Pharmaceutical Association, *Generic Drug Savings in the U.S.*, at 1 (2015), *available at* http://www.gphaonline.org/media/wysiwyg/PDF/GPhA_Savings_Report_2015.pdf.

56. The Hatch-Waxman Act, enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs.[13] Hatch-Waxman allows a manufacturer seeking approval to sell a generic version of a brand drug to file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's NDA, and must show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and is absorbed at the same rate and to the same extent as the brand drug. This establishes that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. The FDA assigns generic drugs that are therapeutically equivalent to and are of the same dosage strength and form as their brand counterpart an "AB" rating.

57. Most drug companies that want to introduce a generic drug to the market file an ANDA with the FDA's Center for Drug Evaluation and Research, Office of Generic Drugs. The only exception is for so-called "authorized generics," which are generics launched under the brand company's NDA but typically priced like other generics.

58. Generic drugs that are bioequivalent to a brand drug (sometimes called the "Reference Listed Drug" or "RLD") are assigned a Therapeutic Equivalence Code ("TE Code"). An oral generic drug product will be coded "AB" if bioequivalence is demonstrated. The purpose of this coding is to allow users to determine whether the FDA has evaluated a particular approved product as therapeutically equivalent to other pharmaceutically

[13] *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

equivalent products and to provide information on the basis of the FDA's evaluations. Thus, generic drugs that are AB-rated to the brand share the same safety and efficacy characteristics and are the same dosage size and form.

C. Desonide Has Been Sold in the United States for Decades

59. Desonide is a low-potency topical corticosteroid that first came to market in the 1970s. Desonide is used to treat swelling, itching and redness caused by a variety of skin conditions. Because of its relatively low potency, Desonide is widely used to treat skin conditions in children and to treat sensitive areas and folds of the skin in adults.

60. Defendants Actavis, Fougera, Perrigo, and Taro have been the primary manufacturers of Desonide available for purchase in the United States. Defendant Sandoz acquired Fougera in 2012.

61. Since at least 1994, manufacturers of generic drugs have had regulatory approval to market generic forms of Desonide. For much of that time, prices for generic forms of Desonide were low because generic manufacturers engaged in robust price competition, as typically occurs among generic drug manufacturers in the absence of collusion.

D. Desonide Prices Increased Dramatically During the Class Period Without Justification

62. Prior to June 2013, the average price in the U.S. paid for Desonide was remarkably stable. Beginning in June 2013, however, Defendants caused the price of Desonide to dramatically increase in unison.

63. The National Association of State Medicaid Directors, National Average Drug Acquisition cost data ("NADAC") "is designed to create a national benchmark that is

reflective of the prices paid by retail community pharmacies to acquire prescription and over-the-counter covered outpatient drugs."[14]

64. The NADAC data shows that between July 2013 and January 2014, Defendants increased their prices for Desonide in tandem by more than 600%, with certain products increasing by nearly 900%.

65. During a single week in July 2013, Defendants Fougera, Perrigo, Sandoz, and Taro collectively raised prices for Desonide more than six-fold, with certain product offerings increasing in price by more than 800%. Whereas, at the beginning of 2013, a 60-gram tube of Desonide cream cost $26.75, by December 12, 2013, the cost was nearly $225.

66. Additional NADAC data as of December 21, 2016 demonstrate that Defendants have maintained prices for Desonide in all of its relevant forms at supracompetitive prices. [15] As of December 2016, the cost of Desonide still remains nearly 500% higher than the cost prior to the June 2013 trade association meeting.[16]

67. There were no market-based justifications for these abrupt price increases, which were not necessitated by increased manufacturing costs, or research and development costs. There were no known raw material shortages affecting the manufacture of Desonide in the United States, nor did demand for Desonide suddenly increase.

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[14] *See* https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/ful-nadac-downloads/nadacmethodology.pdf.

[15] *See* Survey of Retail Prices, *available at* https://www.medicaid.gov/medicaid/prescription-drugs/survey-of-retail-prices/index.html; and National Average Drug Acquisition Cost and NADAC Comparison Data *available at* https://www.medicaid.gov/medicaid/prescription-drugs/pharmacy-pricing/index.html.

[16] *Available at* https://data.medicaid.gov/Drug-Prices/NADAC-as-of-2016-12-28/bg7x-n8ir.

68. Federal law requires drug manufacturers to report potential drug shortages to the FDA, along with the reasons for those shortages, and their expected duration. Defendants made no such reports with respect to Desonide during the Class Period.

69. In a report dated April 21, 2015, Sector & Sovereign Research concluded that: "A plausible explanation is that generic manufacturers . . . are cooperating to raise the prices of products whose characteristics (low sales due to either very low prices or very low volumes) accommodate price inflation."[17]

70. These price increases had a substantial impact on consumers. Letters from members of Congress to generic drug manufacturers included the following:

> This dramatic increase in generic drug prices results in decreased access for patients. According to the National Community Pharmacists Association (NCPA), a 2013 member survey found that pharmacists across the country "have seen huge upswings in generic drug prices that are hurting patients and pharmacies ability to operate" and "77% of pharmacists reported 26 or more instances over the past six months of a large upswing in a generic drug's acquisition price." These price increases have a direct impact on patients' ability to purchase their needed medications. The NCPA survey found that "pharmacists reported patients declining their medication due to increased co-pays," and "84% of pharmacists said that the acquisition price/lagging reimbursement trend is having a 'very significant' impact on their ability to remain in business to continue serving patients."[18]

E. Defendants' Opportunities for Collusion

71. The DOJ is reportedly looking closely at trade associations. According to an intelligence report from Policy and Regulatory Report, a source that was given inside information by someone with knowledge of the DOJ's investigation, the DOJ is looking

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[17] *See US Generic Inflation Continues in 1Q15* (Apr. 21, 2015), *available at* http://www.sector-sovereign.com/abccahmck-us-generic-inflation-continues-in-1q15/.

[18] *See e.g.*, Letter from Sen. Bernard Sanders and Rep. Elijah E. Cummings to Arthur P. Bedrosian, President and Chief Executive Officer, Lannett Company, Inc. (Oct. 2, 2014), *available at* http://www.sanders.senate.gov/download/letter-to-mr-bedrosian-president-and-ceo-lannett-company-inc?inline=file.

closely "at trade associations as part of their investigation as having been one potential avenue for facilitating the collusion between salespeople at different generic producers."

72. Generic drug manufacturers attend industry trade shows throughout the year, including those hosted by the GPhA, the National Association of Chain Drug Stores, the Healthcare Distribution Management Association (now the Healthcare Distribution Alliance), and Efficient Collaborative Retail Marketing.

73. At these conferences and trade shows, Defendants' representatives have opportunities to interact with each other directly, and discuss their respective businesses and customers. Organized recreational and social events, such as golf outings, lunches, cocktail parties, dinners, and other scheduled activities, are held concurrent with many of these conferences and trade shows, and provide further opportunities for conspirators to meet with competitors outside of the usual business setting. Generic drug manufacturer representatives who attend these functions use these opportunities to discuss and share upcoming bids, specific generic drug markets, pricing strategies and pricing terms in their contracts with customers, among other competitively-sensitive information.

74. In addition to these conferences and trade shows, representatives of generic drug manufacturers gather separately, in smaller groups, allowing them to further meet face-to-face with their competitors and discuss their businesses. A large number of generic drug manufacturers, including two of the Defendants, have offices in close proximity to one another in New Jersey, eastern Pennsylvania, or New York, giving them more frequent opportunities to meet and collude. In fact, high-level executives of Defendants gather periodically for what at least some of them refer to as "industry dinners."

75. As a result of these various interactions, Defendants' sales and marketing executives are well aware of their competition and, more importantly, each other's current and future business plans. This familiarity and these opportunities often lead to agreements among competitors to fix prices or to allocate given markets, so as to avoid price competition.

76. Defendants routinely communicate and share information with each other about their bids and pricing strategies. This can include forwarding bid packages received from their customers (*e.g.*, Requests for Proposal) to competitors, either on their own initiative, or at the competitor's request.

77. Defendants also share information regarding the terms of their contracts with customers, including terms relating to pricing, price protection and rebates. Generic drug manufacturers use this information from their competitors to impose higher prices or more onerous terms on their customers, to the ultimate detriment of consumers.

78. Defendants also regularly meet at GPhA events. The GPhA describes itself as "the nation's leading trade association for manufacturers and distributors of generic prescription drugs, manufacturers of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic industry." See http://www.gphaonline.org/about/the-gpha-association/. GPhA was formed in 2000 from the merger of three industry trade associations: GPhA, the National Association of Pharmaceutical Manufacturers, and the National Pharmaceutical Alliance.

79. According to GPhA's website, "GPhA member companies supply approximately 90 percent of the generic prescription drugs dispensed in the U.S. each year." See http://www.gphaonline.org/about/membership. GPhA further claims that, "[b]y becoming part of GPhA, you can participate in shaping the policies that govern the generic

industry and help secure the future of this vital pharmaceutical market segment. In addition, GPhA provides valuable membership services, such as business networking opportunities, educational forums, access to lawmakers and regulators, and peer-to-peer connections." *Id.*

F. Government Responses to Rising Generic Drug Prices

80. As noted above, Defendants' conduct in regards to generic drugs is under investigation by Congress, the DOJ, state attorneys general and others.

81. On October 2, 2014, U.S. Senator Bernie Sanders and U.S. Congressman Elijah Cummings sent letters to several generic drug manufacturers, including Defendant Actavis, requesting detailed sales, marketing and cost information for numerous generic products. Each letter raised significant concerns about the extraordinary price increases that many generic products had experienced since 2013.[19]

82. On November 20, 2014, United States Senator Bernie Sanders' Senate Subcommittee on Primary Health and Aging held a hearing entitled "Why Are Some Generic Drugs Skyrocketing In Price?"[20]

83. Most recently, in December 2016, the United States Senate Special Committee on Aging issued a lengthy report on drug pricing noting that its investigation "uncovered disturbing practices in pharmaceutical drug pricing."[21]

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[19] *Available at* http://www.sanders.senate.gov/newsroom/press-releases/congress-investigating-why-generic-drug-prices-are-skyrocketing.

[20] *See, e.g.*, U.S. Congress Press Release, *Congressional Panel to Probe Generic Drug Price Hikes* (Nov. 11, 2014), *available at* https://democrats-oversight.house.gov/news/press-releases/congressional-panel-to-probe-generic-drug-price-hikes.

[21] United States Senate Special Committee on Aging, Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System (Dec. 2016), *available at* https://www.collins.senate.gov/sites/default/files/DP%20Report.pdf.

84. No later than November 3, 2014, as noted above, the DOJ opened a wide-ranging grand jury investigation into the marketing and pricing practices of generic drugs, which has resulted in the issuance of grand jury subpoenas several generic drug manufacturers, including all Defendants and/or their affiliates. The DOJ is now conducting a wide-ranging criminal investigation into collusion among generic drug companies. According to BLOOMBERG NEWS, the investigation encompasses more than 12 companies and at least 24 generic drugs. *See*, https://www.bloomberg.com/news/articles/2016-12-22/widespread-drug-price-increases-point-to-collusion-study-finds.

85. A source at the Policy and Regulatory Report says "prosecutors see the case much like its antitrust probe of the auto parts industry, which has gone on for years and morphed into the department's largest criminal antitrust probe ever. Like in that case, prosecutors expect 'to move from one drug to another in a similar cascading fashion.'"[22]

86. Some Defendants have confirmed that they have been served with federal grand jury subpoenas and subpoenas issued by the Connecticut Office of the Attorney General.

87. On June 25, 2015 Actavis parent Allergan plc disclosed in public filings that Actavis had received a subpoena from the DOJ "seeking information relating to the marketing and pricing of certain of the Company's generic products and communications with competitors about such products."

88. On September 9, 2016, Defendant Taro disclosed in an SEC filing that it "as well as two senior officers in its commercial team, received grand jury subpoenas from the

[22] Eric Palmer, *DOJ criminal probe takes a look at trade associations*, FIERCEPHARMA (Jul. 10, 2015), *available at* http://www.fiercepharma.com/regulatory/doj-criminal-probe-takes-a-look-at-trade-associations.

United States Department of Justice, Antitrust Division, seeking documents relating to corporate and employee records, generic pharmaceutical products and pricing, communications with competitors and others regarding the sale of generic pharmaceutical products, and certain other related matters."

89. According to a Bloomberg News article, Sandoz has confirmed that it received a subpoena from the DOJ in March 2016, and stated that it believed the subpoena was related to "the industry-wide investigation into generic drug pricing in the U.S."[23]

90. The fact that these companies and/or their employees received subpoenas from a federal grand jury is significant, as is reflected in Chapter 3 of the 2014 edition of the DOJ's Antitrust Division Manual.[24] Section F.1 of that chapter notes that "staff should consider carefully the likelihood that, if a grand jury investigation developed evidence confirming the alleged anticompetitive conduct, the Division would proceed with a criminal prosecution." *Id.* at III-82. The staff request needs to be approved by the relevant field chief and is then sent to the Antitrust Criminal Enforcement Division. *Id.* "The DAAG [Deputy Assistant Attorney General] for Operations, the Criminal DAAG, and the Director of Criminal Enforcement will make a recommendation to the Assistant Attorney General. If approved by the Assistant Attorney General, letters of authority are issued for all attorneys who will participate in the grand jury investigation." *Id.* at III-83. "The investigation should be conducted by a grand jury in a judicial district where venue lies for the offense, such as a district from or to which price-fixed sales were made or where

[23] https://www.bloomberg.com/news/articles/2016-11-17/nypd-union-goes-after-drug-prices-amid-doj-pharma-investigation.

[24] DOJ Antitrust Division Manual, *available at* http://www.justice.gov/atr/public/divisionmanual/chapter3.pdf.

conspiratorial communications occurred." *Id.* Thus, Defendants' and their representatives' receipt of federal grand jury subpoenas is an indication that antitrust offenses have occurred.

91. If there is a leniency applicant involved in the DOJ generic drug investigation, there is still greater indication that antitrust offenses have occurred. The DOJ notes on its website that the leniency applicant must admit to a criminal violation of the antitrust laws before receiving a conditional leniency letter.

> The Division's leniency policies were established for corporations and individuals "reporting their illegal antitrust activity," and the policies protect leniency recipients from criminal conviction. Thus, the applicant must admit its participation in a criminal antitrust violation involving price fixing, bid rigging, capacity restriction, or allocation of markets, customers, or sales or production volumes before it will receive a conditional leniency letter. Applicants that have not engaged in criminal violations of the antitrust laws have no need to receive leniency protection from a criminal violation and will receive no benefit from the leniency program.[25]

92. The DOJ further provides that the leniency applicant must also satisfy the following condition, among others, to avail itself of the government's leniency: "[t]he confession of wrongdoing is truly a corporate act, as opposed to isolated confessions of individual executives or officials." *Id*.

93. The DOJ is poised to issue criminal indictments against various companies and individuals growing out this investigation and, as indicated above, issued its first two indictments on December 12, 2016. On December 14, 2016, BLOOMBERG reported that "[t]he Justice Department accused two executives of colluding with other generic pharmaceutical companies to fix prices, the first criminal charges stemming from a sweeping two-year

[25] Frequently Asked Questions Regarding The Antitrust Division's Leniency Program, *available at* http://www.justice.gov/atr/frequently-asked-questions-regarding-antitrust-divisions-leniency-program.

investigation. Jeffrey Glazer, a former chief executive officer of Heritage Pharmaceuticals Inc., and Jason Malek, an ex-president, were charged in Philadelphia on Wednesday, according to court filings."[26]

94. Twenty states attorneys general also filed their first action (relating to the generic drugs Glyburide and Doxycycline) based on their investigation into generic drug pricing on December 15, 2016.[27] They have indicated that more actions are likely to follow, specifically alleging that they "have uncovered a wide-ranging series of conspiracies implicating numerous different drugs and competitors, which will be acted upon at the appropriate time..." The states attorneys general describe these conspiracies as "schemes to fix and maintain prices, allocate markets and otherwise thwart competition" and explain that they are carried out by generic companies through their senior executives who "exploit their interactions at various and frequent industry trade shows, customer conferences and other similar events, to develop relationships and sow the seeds for their illegal agreements. The anticompetitive agreements are further refined and coordinated at regular 'industry dinners', 'girls nights out', lunches, parties, and numerous and frequent telephone calls, emails and text messages."[28]

95. Connecticut's attorney general George C. Jepsen commented on the suit that it was "just the tip of the iceberg" and stressed that "our investigation is continuing, and it

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[26] Tom Schoenberg, *U.S. Generic Drug Probe Seen Expanding After Guilty Pleas*, BLOOMBERG (Dec. 14, 2016), *available at* https://www.bloomberg.com/news/articles/2016-12-14/u-s-files-first-charges-in-generic-drug-price-fixing-probe.

[27] Complaint, *State of Connecticut v. Aurobindo Pharma USA*, 16-cv-2056-VLB (D. Conn. Dec. 15, 2016), ECF No. 1.

[28] *Id.* at paragraphs 7-8.

goes way beyond the two drugs in this lawsuit" and "involves many more companies" than were named in the first complaint.[29]

G. The Desonide Market is Conducive to an Effective Conspiracy.

96. Characteristics specific to the market for Desonide in the United States make it conducive to a price-fixing agreement.

97. **The Market is Highly Concentrated:** A concentrated market is more susceptible to collusion and other anticompetitive practices. The Desonide market is highly concentrated and is dominated by the Defendants. Therefore, elaborate communications, quick to be detected, would not have been necessary to enable pricing to be coordinated.

98. **The Market has High Barriers to Entry:** Conspiracies that raise product prices above competitive levels will, all things being equal, attract to the relevant market new firms seeking to benefit from supracompetitive prices. But when barriers to entering the market are significant, new firms are less likely to do so. Barriers to entry thereby facilitate the maintenance of a price-fixing conspiracy. Costs of manufacture, intellectual property, and expenses related to regulatory oversight are barriers to entry.

99. As the dominant players in the Desonide market, Defendants were able to fix, raise, and maintain their prices for Desonide without competitive threats from rival generic drug manufacturers.

100. **Demand for Desonide is Inelastic:** "Elasticity" is a term that describes the sensitivity of demand for a product to changes in its price. Demand is "inelastic" if an increase in its price results in a relativity small decline in demand for the product. Demand

[29] Katie Thomas, *20 States Accuse Generic Drug Companies of Price Fixing*, THE NEW YORK TIMES (Dec. 15, 2016), *available at* http://www.nytimes.com/2016/12/15/business/generic-drug-price-lawsuit-teva-mylan.html.

is inelastic in markets—such as the Desonide market—in which customers cannot readily substitute alternative products, or do without a product altogether.

101. For competitors to profit from colluding to raise prices above competitive levels, demand for their product must be relatively inelastic at competitive prices. Otherwise, increased prices would reduce their sales as customers abandoned their products. Inelastic demand thus facilitates collusion.

102. Demand for Desonide is highly inelastic. A meaningful increase in the price for Desonide would not induce purchasers to switch to another product in significant numbers, as the there is no reasonable substitute for Desonide available at a lower price.

103. **Desonide is a Fungible Product:** Because all Desonide is the same, price is the predominant factor driving customers' purchasing decisions. The interchangeability of Desonide products facilitated Defendants' conspiracy by enabling coordination on price that would be more difficult if Defendants sold products that varied in composition and/or performance.

104. **Defendants Had Ample Opportunities To Meet and Conspire:** Defendants had numerous opportunities to conspire in person under the guise of legitimate business meetings. In particular, Defendants are members of the GPhA, and attend other industry events and meetings, which provide opportunities to communicate. Defendants' representatives regularly attended meetings of GphA and meetings of other trade associations during the Class Period. The DOJ is reportedly investigating trade associations like GPhA as a potential avenue for facilitating collusion among generic drug manufacturers as part of its ongoing investigation into anticompetitive pricing activities in generic drug markets.

ANTITRUST INJURY

105. During the Class Period, Plaintiff and Class Members purchased Desonide directly from Defendants. As a result of the Defendants' anticompetitive conduct, Plaintiff and Class Members paid more for Desonide than they would have and thus suffered substantial damages. This is a cognizable antitrust injury and constitutes harm to competition under the federal antitrust laws.

106. Because Defendants' unlawful conduct has successfully restrained competition in the market, Plaintiff and Class Members have sustained, and continue to sustain, significant losses in the form of artificially inflated prices paid to Defendants. The full amount of such damages will be calculated after discovery and upon proof at trial.

107. Defendants' anticompetitive conduct is ongoing, and as a result Plaintiff and the Class continue to pay supracompetitive prices for Desonide.

CLAIM FOR RELIEF

VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1

108. Plaintiff incorporates and re-alleges, as though fully set forth herein, each of the paragraphs set forth above.

109. Defendants are *per se* liable under Section 1 of the Sherman Act, 15 U.S.C. § 1, for the injuries and damages caused by their contract, combination, and conspiracy in restraint of trade as alleged herein.

110. There is no legitimate, non-pretextual, procompetitive business justification for Defendants' conspiracy that outweighs its harmful effect. Even if there were some conceivable justification, the conspiracy is broader than necessary to achieve such a purpose.

111. As set forth above, in violation of Section 1 of the Sherman Antitrust Act, Defendants entered into agreements with one another as to the output and pricing of Desonide in the United States. This conspiracy was *per se* unlawful price-fixing, or alternatively, was an unlawful restraint of trade under the rule of reason.

112. Each Defendant has committed at least one overt act to further the conspiracy alleged in this Complaint.

113. The conspiracy had its intended effect, as Defendants benefited from their collusion and the restraint of competition, both of which artificially inf1ated the prices of Desonide, as described herein.

114. As a result of Defendants' unlawful conduct, Plaintiff and Class Members have been injured in their business and property in that they have paid more for Desonide than they otherwise would have paid in the absence of Defendants' unlawful conduct. The full amount of such damages is presently unknown but will be determined after discovery and upon proof at trial.

115. Defendants' unlawful conduct as alleged herein poses a significant, continuing threat of antitrust injury for which injunctive relief is appropriate under Section 16 of the Clayton Act.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff and Class Members pray for relief as set forth below:

A. Certification of the action as a Class Action pursuant to Federal Rule of Civil Procedure 23, and appointment of Plaintiff as Class Representative and its counsel of record as Class Counsel;

B. Permanent injunctive relief that enjoins Defendants from violating the antitrust

laws and requires them to take affirmative steps to dissipate the effects of their violations;

C. That acts alleged herein be adjudged and decreed to be unlawful restraints of trade in violation of the Sherman Act, 15 U.S.C. § 1;

D. A judgment against Defendants, jointly and severally, for the damages sustained by Plaintiff and the Class defined herein, and for any additional damages, penalties, and other monetary relief provided by applicable law, including treble damages;

E. By awarding Plaintiff and Class Members pre-judgment and post-judgment interest as provided by law, and that such interest be awarded at the highest legal rate from and after the date of service of the Complaint in this action;

F. The costs of this suit, including reasonable attorney fees; and

G. Such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff, on behalf of itself and others similarly situated, hereby requests a jury trial, pursuant to Federal Rule of Civil Procedure 38, on any and all claims so triable.

Dated: January 12, 2016

Respectfully submitted,

/s/ Linda P. Nussbaum

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